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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|----------------------------|------------------------|
| 10/578,800 | 05/09/2006 | Giancarlo Tamerlani | 207,580 | 8712 |
| <div><div>759007/30/2007</div><div>Jay S Cinamon Abelman Frayne and Schwab 666 Third Avenue New York, NY 10017-5621</div></div> | | | | |
| | | | EXAMINER BLAND, LAYLA D | |
| | | | ART UNIT 1623 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/578,800

Applicant(s)

TAMERLANI ET AL.

Examiner

Layla Bland

Art Unit

1609

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 May 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/19/2006</u> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This office action is a correction to the office action dated July 10, 2007. In the office action dated July 10, 2007, rejections which were intended to be made under 35 U.S.C. 103(a) were inadvertently labeled as rejections under 35 U.S.C. 102(b). The error is corrected herein.

This application is a national stage entry of PCT/EP04/52900, filed November 10, 2004, and claims priority to Italian Application No. FI2003A000288, filed November 10, 2003. Applicant's election, with traverse, of Group I, claims 1 and 3-23, dated May 25, 2007, is acknowledged. In the response dated May 25, 2007, Mr. Cinamon asserts that the steps of acylation and chlorination constitute a contribution over the prior art and therefore there is no lack of unity of invention. The examiner does not agree that these steps are novel or non-obvious, as will be discussed below. However, upon further consideration of the claims as currently presented, it is clear that the examination of Group I will encompass the examination of Group II, so the restriction requirement is withdrawn. Claims 1-36 are pending in this application and are examined on the merits herein.

Claim Objections

Claim 20 is objected to because of the following informalities: "1,5 moles" should be "1.5 moles." Appropriate correction is required.

Claims 6, 20, 22 and 27 are objected to because of the following informalities:
claim 6 (and similarly claims 20, 22 and 27) is drawn to a process according to claim 1, wherein the reaction is carried out using from 1 to 1.5 moles of sodium metaperiodate *compared to* the compound of formula (III). "Moles" is an absolute term, not a comparative term. Suggested language for the claim could be "wherein the reaction is carried out using from 1 to 1.5 equivalents of sodium metaperiodate compared to the compound of formula (III)" or "wherein the reaction is carried out using from 1 to 1.5 moles of sodium metaperiodate per mole of the compound of formula (III)."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

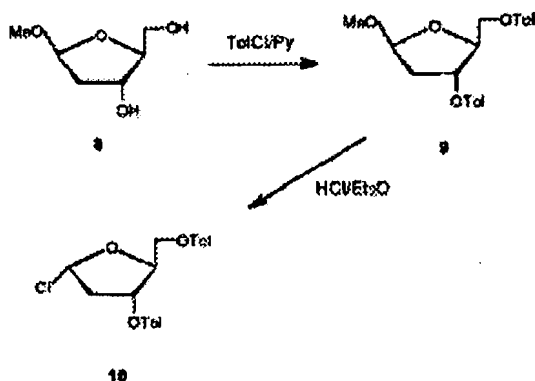
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2, 24-27, 31, 34 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Zhang et al. (Nucleosides & Nucleotides 1999, 18(11 & 12), 2357-2365, PTO-1449 submitted December 19, 2006).

Zhang et al. teach the following reaction:

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Methyl 2-deoxy-β-L-erythro-pentofuranose (60.8 mmol) was dissolved in pyridine (a tertiary amine and an aprotic solvent), cooled in an ice-water bath, and treated with *p*-toluoyl chloride (an acyl chloride wherein R' is an aryl group substituted with a methyl group) (136 mmol) to give methyl 2-deoxy-3,5-di-O-*p*-toluoyl-L-erythro-pentofuranose. Methyl 2-deoxy-3,5-di-O-*p*-toluoyl-L-erythro-pentofuranose (57.3 mmol) was dissolved in dry ether, cooled to 0°C in an ice bath, and dry HCl was bubbled in. The resulting precipitate was filtered and dried over vacuum to give 2-deoxy-3,5-di-O-*p*-toluoyl-α-L-erythro-pentofuranosyl chloride. These reaction conditions meet the limitations of claims 2, 24-27, 31, 34 and 35.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 28-30 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. (Nucleosides & Nucleotides 1999, 18(11 & 12), 2357-2365, PTO-1449 submitted December 19, 2006) in view of Mormann et al. (Acta Polym. 1999, 50, 20-27).

Zhang et al. teach as set forth above.

Zhang et al. do not teach the use of triethylamine, the solvents of claims 29 and 30 or acylation at 60°C.

Mormann et al. teach the acylation of partially silylated trimethylcellulose with acid chlorides and triethylamine in toluene or dichloromethane solvent. The temperature was kept below 50°C in order to prevent cleavage of Si-O bonds [Section 2.2]. High temperature acylation is faster than room temperature acylation [Section 2.3].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use triethylamine in toluene for the acylation of carbohydrates. The skilled artisan would have been motivated to do so because Mormann et al. teach the acylation of trimethylcellulose using an acid chloride and triethylamine in toluene. Mormann et al. also teach the use of elevated temperatures for the acylation reaction and teach that the temperature should be adjusted according to the presence of sensitive functional groups, which is considered within the skill of one skilled in the art.

It is noted that, in the method taught by Fox et al. (Journal of the American Chemical Society 1961, 83, 4066-70), the product of the acylation reaction is not purified by column chromatography before being used in the subsequent chlorination reaction.

Claims 33 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. (Nucleosides & Nucleotides 1999, 18(11 & 12), 2357-2365, PTO-1449 submitted December 19, 2006) in view of Fox et al. (Journal of the American Chemical Society 1961, 83, 4066-50).

Zhang et al. teach as set forth above.

Zhang et al. do not teach a chlorination reaction wherein acetyl chloride is present, or the chlorination reaction in the presence of toluene.

Fox et al. teach the chlorination of methyl 3,5-di-O-(*p*-chlorobenzoyl)-2-deoxy- D-ribofuranoside wherein the starting material was dissolved in ether, cooled, and treated with acetic acid and HCl [Experimental, first paragraph].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use acetic acid in the chlorination taught by Zhang et al. The skilled artisan would have been motivated to do so because Fox et al. teach chlorination of a very similar ribofuranoside compound using acetyl chloride and HCl.

One of ordinary skill in the art would realize that toluene and diethyl ether are both non-polar solvents with similar dielectric constants and can be used interchangeably in the chlorination reaction.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA)

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1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Allowable Subject Matter

Claims 1 and 3-23 are allowable as being drawn to a novel process for the production of 1-chloro-3,5-di-O-acyl-deoxy-L-ribofuranoside derivatives. Zhang et al. teach as set forth above, but do not teach or suggest the claimed method of making the O-methyl-2-deoxy-L-ribofuranose of formula (V).

Conclusion

No claims are allowed in this application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Bland whose telephone number is (571) 272-9572. The examiner can normally be reached on M-R 8:00AM-5:00PM UST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang, can be reached on (571) 272-0267. The fax phone


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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Layla Bland
Patent Examiner
Art Unit 1623
July 3, 2007

Shaojia Anna Jiang

 8/3/07
Supervisory Patent Examiner
Art Unit 1623